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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Oxytetracycline and Neomycin; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations concerning antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals. The entry for type A medicated article oxytetracycline and neomycin is amended to reflect that the sponsor of the product is Pfizer, Inc., not Hoffman-La Roche, Inc. Also, the entry for use of type A medicated article oxytetracycline and neomycin base for type C turkey feeds, when used as an aid in reducing mortality in birds which have suffered an attack of air-sacculitis, is amended to change the neomycin use level from 35 to 100 grams (g) of neomycin base per ton of feed to 35 to 105 g/ton.

EFFECTIVE DATE: (*Insert date of publication in the* **Federal Register.)**

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pi., Rockville, MD 20855,301-827-0212.

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations in 21 CFR 558. 15(g)(l) concerning antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals. Previously, for use of type A medicated article oxytetracycline and neomycin, FDA had amended the regulations to remove several entries for Pfizer, Inc. (see 61 FR 51588 at 51590, October

3, 1996). The amendment failed to change the "do" for the remaining entry to "Pfizer, Inc." This document provides for that change.

Also, in paragraph (g)(2), in the entry for drug sponsors "Pfizer, Pennfield, and VPO," for type A medicated article ' 'Oxytetracycline and neomycin base, " in species "Turkeys (first 4 weeks)," the use level for use as an aid in reducing mortality in birds which have suffered an attack of air-sacculitis is changed. The level subject to interim approval has been recalculated and is changed from '{lOO to 150 g/ton and 35 to 100 g/ton" to "100 to 150 g/ton and 35 to 105 glton".

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegate to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, **371.**

§ 558.15 [Amended]

2. Section 558.15 *Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals* is amended in the table, in paragraph (g)(l), in the column "Drug sponsor" by removing the "do" following the entry "Hoffman La-Roche, Inc." and adding in its place "Pfizer, Inc."; and in the table in paragraph (g)(2) in the entry for "Pfizer, Inc., Pennfield Oil Co., and VPO, Inc. " for Type A medicated article ' 'Oxytetracycline and neomycin base," for the species "Turkeys (first 4 weeks)," by

removing the use level ''100 to 150 g/ton and 35 to 100 g/ton'' and adding in its place ''100 to 150 g/ton and **35** to 105 g/ton. ''

Dated: Dec. 18, 1998

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Andrew J. Beaulieu
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Office of New Animal Drug Evaluation
Center for Veterinary Medicine

HS

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